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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09 132,521	08 11 1998	YOSHIYUKI NAGAI	50026 008001	9549

7590 08 13 2003

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

33

DATE MAILED: 08 13 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/132,521

Examiner

Joseph T. Weitach

Applicant(s)

NAGAI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12, 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This application is an original application filed August 11, 1998.

Applicants' amendment filed May 22, 2003, paper number 31, has been received and entered. The specification has been amended. Claims 1-3, 6-8, 10-12 and 14-23 have been amended. Claims 1-8, 10-12 and 14-23 are pending and currently under examination.

Response to Amendment

The declaration filed under 37 CFR 1.132 filed May 22, 2003, paper number 30, is sufficient to overcome the rejection of claims based upon the Shioda *et al.* reference.

Specification

The objection to the specification because nucleotide sequences contained in this application did not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 is withdrawn.

The amendments to the specification and the filing of sequence listing, entered as paper number 32 has obviated the basis of the objection.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-12, 14 and 15-23 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

Amendments to the claims to delete the term "soluble" has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11, 12, 14 and 15-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims has obviated the basis of each of the specific rejections previously set forth.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, 7, 11, 14, 16, 20 and 21 rejected under 35 U.S.C. 102(a) as being anticipated by Shioda *et al.* (AIDS Res, 11:167, 1997) is withdrawn.

The declaration of Dr. Yoshiyuki Nagai filed under 37 CFR 1.132 states that Shioda Moriya and Nagai are the inventors of the claimed invention and provides a description of contribution of each of the other co-authors to the published work. Upon review of the declaration, Applicants' statements are sufficient to obviate the use of the teachings of the Shioda *et al.* reference because it is not published more than a year before the filing date of the instant application and it is not by another.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-12 and 14-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Yu *et al.* and Bleul *et al.* in view of Hasaan *et al.* (J. Gen. Vir. 78:2813-2820, 1997).

Applicants note that the claims require that the chemokine produced by the cell is biologically active, and argue that the successful use of a Sendai virus expression system has been over-simplified. Applicants argue that Yu *et al.* had mixed results when expressing proteins using a Sendai virus and that the successful production of one protein, in particular gp120, would not provide adequate expectation of success for the production of another protein, such as a chemokine as instantly claimed. It is argued that the teaching of Hasaan *et al.* does not remedy this potential limitation and that Czaplewski *et al.* does not qualify as prior art therefore there is no reference which supports that biologically active chemokines could be produced by Sendai virus system (page 11-12). Finally, Applicants argue that Bleul *et al.* discusses chemokines but not Sendai virus vectors, and that based on the unpredictability of using Sendai virus vectors one would not motivated to try to synthesize a chemokine using such a system (page 13). See Applicants amendment pages 11-13. Applicants arguments have been fully considered but not found persuasive.

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Initially, it is noted that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a reasonable expectation of success. See *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988). Further, the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971), and for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988).

As previously set summarized, the results presented in Yu *et al.* clearly indicate that gp120 can be expressed by various cell types at various levels (see for example page 460; Table 1), and that the protein produced is a functional protein (see results in figure 4), and Hasan *et al.* clearly teach that the Sendai virus is capable of expressing an active form of the luciferase protein (see results in Table 2 and Figure 2). Examiner would agree that while any expression system may produce such large amounts of protein that insoluble precipitates are formed, the evidence provided by Yu *et al.* and Hasan *et al.* clearly teach that biologically active proteins can be produced by the Sendai virus vector system. In this case the evidence of record provide a clear expectation of success, even for proteins such as luciferase which when produced in large amounts may appear to be partly insoluble. Examiner acknowledges that Czaplowski *et al.* is a post filing reference, however as the claims are amended to encompass only 'a biologically active form' of a protein produced it is not specifically relied upon. However it would serve as a

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summary and evidence of the properties of known chemokines being soluble. It is noted that the present specification provides no specific sequences for the chemokines contemplated or specific sequences for expressing these chemokine sequences, and relies on the art for these teachings and the inherent properties of these molecules for the success of producing active molecules.

Additionally, the aggregation of any given protein is an effect of external factors separate from the ability of a vector, in this case a Sendai virus vector, to express any given polynucleotide.

Applicants appear to be relying on the fact that there is no single reference that anticipates the instantly claimed invention, and that because the disclosure is the first to demonstrate that using a known expression system to express known genes of interest that combining these teachings would not be obvious or successful. As noted previously, the art of record teaches that the Sendai virus has been used successfully to express other proteins in various cell types, and both Yu *et al.* and Hasan *et al.* each specifically suggest that the Sendai virus will be "an excellent tool for foreign gene expression" (Hasan page 2819, final paragraph). Yu *et al.* conclude from their use of the Sendai virus vector that the characteristics of the Sendai virus make it a useful tool for the delivery and expression of other polynucleotide sequences (page 463; second column). Therefore, clearly there is motivation to use a Sendai vector for expression of a protein of interest and a general expectation of success to produce the protein. The reliance of Bleul *et al.* is for the teaching that the SDF-1 had already been cloned and characterized (page 830; top of first column), and that the chemokine SDF-1 blocks HIV entry affecting HIV infection and the ability of the virus to replicate. In light of the specific motivation of Yu *et al.* and Hasan *et al.*

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teaching that Sendai virus has realistic utility and broad application in to express sufficient amounts of a protein and the specific teaching evaluating the effect and teaching of Bleul *et al.* that SDF-1 for affecting HIV affected cells, it would have been obvious to one of ordinary skill in the art to combine the teachings to express and evaluate the effect of SDF-1 and other related chemokines in various cell types. As detailed above, there would have been a reasonable expectation of success by one of ordinary skill in the art to express a soluble chemokine using a Sendai virus vector.

Therefore, for the reasons above and of record, it is maintained that the invention is *prima facie* obvious.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630